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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,093	12/06/2004	Frank Seibertz	RO0953US(#90568)	1122
7590 D Peter Hochberg Baker Building 6th Floor 1940 East 6th Street Cleveland, OH 44114			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 11/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,093	Applicant(s) SEIBERTZ ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 24-41 and 47-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-23 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06 Dec 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to the Restriction Requirement

Claims 7-10, 24-41 and 47-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 29, 2008.

Applicant's election with traverse of Group I in the reply filed on July 29, 2008 is acknowledged. The traversal is on the ground(s) that the compositions are substantially free from water is opposite the cited art which teaches aqueous solutions. This is not found persuasive because the claims recite "substantially free". When looking to the instant disclosure, water may be present in a small amount making the compositions aqueous.

The requirement is still deemed proper and is therefore made FINAL.

Claims

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-6, 11-23 and 42-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "film-shaped preparation". It cannot be ascertained what is meant by "film-shaped" such as is the term "shaped" directed to its dimensions such as thickness and length or does this refer to the shape such as circle or square. The attachment of "shaped" makes the otherwise definite term "film" indefinite.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-23 and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinity et al. (US 2001/0006677).

McGinity et al. disclose effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration. The formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes (paragraph 0016) encompassing claim 13. The films may be single layer or multilayer films. The films comprise a water soluble or swellable film binder, and active ingredient, a plasticizer and an effervescent couple (paragraph 0016). The effervescent couple produces a gas, such as carbon dioxide or oxygen, when in water (paragraph

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0032). Effervescent components include sodium bicarbonate and sodium carbonate (paragraph 0076) and acids such as citric acid and maleic acid (paragraph 0073). The film will dissolve/disintegrate at a controlled rate when exposed to a water containing solution. The thickness of the film ranges from 0.1 mm to 2 mm (paragraph 0033) encompassing claims 18, 45 and 46. As a single layer, the film will be the product of a single extrusion. When a multi-layered film is involved, the different layers can be co-extruded in an extruder equipped with two die slots and then laminated together; alternatively, the different layers can be separately extruded one on the other (paragraph 0045). Flavorings include peppermint oil, which comprises menthol¹. The components are mixed together, encompassing suspending the components in a suspending agent as recited in the instant claims (paragraph 0094).

In regards of the process claims, it is concluded that in the case of a single layer, when the hot melt forms a film, the surface it extruded upon becomes dry. In the case of the two layers, the first layer that the second layer is extruded upon may be considered the substrate and becomes dry when the two layers form a film.

Claims 1-6, 11-23 and 42-46 are rejected.

Claims 7-10, 24-41 and 47-82 are withdrawn.

No claims allowed.

¹ Blackwell et al., US 4,440,790, disclose peppermint comprises menthol (col. 1, lines 12-18).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

***/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612***